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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,962	10/03/2000	Mark B. Lyles	068351.0110	4536

7590 08/25/2004

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/677,962

Applicant(s)

LYLES ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 7-22, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seare, Jr. (5,681,572) in view of Hatahira (4,503,157). Seare, Jr. discloses the invention substantially as claimed. Seare, Jr. discloses, in col. 9, lines 9-43, col. 14, line 20 to col. 15, lines 9 and col. 15, lines 54-65, a drug delivery system with a composition manufactured from ceramic fibers or particles, one or more drugs (including antibiotics), one or more biodegradable polymers or fusion compounds (polyvinyl alcohol, polyglycolic acid, or polylactic acid), cells (cell culture), nutrients (e.g., dextrose), where the composition can have various porosities or densities. However, Seare, Jr. does not disclose a composition manufactured from silica fibers and carbon fibers and a density in the ranges as claimed. Seare, Jr. does not disclose spherical

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particles having a mean diameter of about 300 microns to about 500 microns. Seare, Jr. also does not disclose the drugs as claimed in claims 17-20. Hatahira teaches, in col. 4, line 42 to col. 5, line 29, the use of ceramic silica fibers and carbon fibers in a porous material product. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Hatahira, to apply silica in the system of Seare, Jr. Silica and carbon are biocompatible materials that can optimize porous structures for cell growth and drug delivery. Moreover, these fiber materials exhibit reinforcing effects not deteriorated in the course of baking during the manufacture of the product. The types of drugs, particle size, and the density of the composition are matters of design choice, so the drugs as claimed, spherical particles having a mean diameter of about 300 microns to about 500 microns, or a density in the ranges as claimed can be chosen according to the desired mechanical strength and therapeutic effects desired from the drug delivery system.

3. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seare, Jr. in view of Hatahira as applied to claim 7 above, and further in view of Corwin (4,932,099). Seare, Jr. in view of Hatahira discloses the invention substantially as claimed. The combination discloses a drug delivery system that can comprise a composite or mixture (see specifically Hatahira's teaching in col. 5, lines 25-29) of alumina fibers, silica fibers, silicon carbide fibers, carbon fibers, and boron-coated fibers; as well as a density as claimed. However, the combination does not specifically disclose the application of boron nitride. Corwin teaches, in col. 4, lines 7-29, boron nitride fibers among ceramic fibers usable in a composite. It would have been obvious

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to one of ordinary skill in the art at the time the invention was made, in view of Corwin, to include boron nitride fibers in the product of Seare, Jr. in view of Hatahira. Such fibers not only exhibit excellent strength-to-weight properties, the fibers can withstand high temperatures used in the manufacture of the product.

***Response to Amendment***

4. Applicant's arguments filed on May 27, 2004 with respect to claims 7-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Homsy (3,992,725), Nakajima et al. (5,098,842), Brun et al (5,552,352) teach products comprising fibers.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo  
Primary Examiner

August 23, 2004